UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,595	04/27/2006	Todd Charlton Sacktor	15878	6263
272 7590 12/10/2008 SCULLY, SCOTT, MURPHY & PRESSER, P.C. 400 GARDEN CITY PLAZA SUITE 300 GARDEN CITY, NY 11530			EXAMINER	
			MACFARLANE, STACEY NEE	
			ART UNIT	PAPER NUMBER
			1649	
			MAIL DATE	DELIVERY MODE
			12/10/2008	PAPER

# Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)				
Office Action Occurrence	10/533,595	SACKTOR ET AL.				
Office Action Summary	Examiner	Art Unit				
	STACEY MACFARLANE	1649				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1) Responsive to communication(s) filed on 10 Oc	ctober 2008					
• • • • • • • • • • • • • • • • • • • •	action is non-final.					
<i>,</i> —	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
	closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims						
• 4)⊠ Claim(s) <u>1-9,12,14-16,18-22 and 24-37</u> is/are pending in the application.						
4a) Of the above claim(s) <u>1-9,12,14-16,18-21 and 24-37</u> is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>22</u> is/are rejected.						
7) Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction and/or	election requirement.					
Application Papers						
··· <u> </u>						
9) The specification is objected to by the Examiner.						
10) ☐ The drawing(s) filed on is/are: a) ☐ acce						
Applicant may not request that any objection to the o						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>						
Attachment(s)	_					
1) Notice of References Cited (PTO-892)  4) Interview Summary (PTO-413)  Paper No(s)/Mail Date						
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date  Notice of Informal Patent Application						
Paper No(s)/Mail Date 6) Other:						

Art Unit: 1649

### **DETAILED ACTION**

## Response to Amendment

1. Claims 1-9, 12, 14-16, 18-22 and 24-37 are pending. Claim 22 has been amended, and claim 23 cancelled, as requested in the amendment filed on October 10, 2008.

Claims 1-9, 12, 14-16, 18-21 and 24-37 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected subject matter, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper filed on February 25, 2008.

Claim 22 is under examination in the instant office action.

- 2. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.
- 3. Applicant's arguments filed on October 10, 2008 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

### Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 22 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, for reasons of record in the previous Office action mailed April 11, 2008.

Art Unit: 1649

6. On pages 10 and 11 of Remarks filed October 1, 2008, Applicant traverses the rejection on the grounds that, as amended to recite an antibody which binds an "atypical isoform" of a protein kinase C, wherein the protein kinase C is protein kinase M zeta", delineates the antibody against specific molecules with known structure, physical and chemical properties, functional characteristics. While this has been carefully considered it is not found persuasive to overcome the rejection for the following reasons.

7. As amended, the recitation of "atypical isoforms" within the claim does not distinguish the antigen to which the antibody binds. In the recent decision the Board upheld the written description rejection for an antibody on the basis that the antigen was not adequately described (Ex parte Alonso, No. 2006-2148 (B.P.A.I. July 25, 2007)). Alonso's claim is drawn to "a monoclonal antibody idiotypic to the neurofibrosarcoma of said human." The Board states, "The specification teaches nothing about the structure, epitope characterization, binding affinity, specificity, or pharmacological properties common to the large family of antibodies implicated by the method". As is the case here, the specification has not adequately described the genus of antibodies encompassed by the claim. Therefore, the rejection is maintained.

# Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

<sup>(</sup>b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 1649

9. Claim 22 stands as rejected under 35 U.S.C. 102(b) as being anticipated by Naik (2000) for reasons of record in the Office action mailed April 11, 2008.

10. On page 11 of Remarks, Applicant traverses the rejection on the grounds that, "The Examiner alleges that Naik et al. teach a PKC primary antisera that binds to PKM $\zeta$ . Thus, the Examiner contends that the prior art anticipates the antibody product of the claims. Applicants disagree. In fact, the antisera disclosed in Naik et al. does not bind to the protein PKM $\zeta$ , as presently claimed. Thus, the rejection of claims 22 and 23 under 35 U.S.C. § 102(b) is overcome and withdrawal thereof is respectfully requested." While this argument has been fully considered it is not found persuasive for the following reasons.

Section 714.02 of the MPEP states, "The reply must present arguments pointing out the specific distinctions believed to render the claims, including any newly presented claims, patentable over any applied references. A general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references does not comply with the requirements of this section.

Examiner maintains that the Naik prior art teaches PKC antisera comprising antibodies that bind to PKM $\zeta$ . Therefore, the antibody of the instant claims fails to distinguish over that of the prior art and the rejection on the grounds of anticipation is maintained.

Art Unit: 1649

### Conclusion

11. No Claim is allowed.

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to STACEY MACFARLANE whose telephone number is (571)270-3057. The examiner can normally be reached on M,W and ALT F 7 am to 3:30, T & R 5:30 -5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1649

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Stacey MacFarlane Examiner Art Unit 1649

/Olga N. Chernyshev/ Primary Examiner, Art Unit 1649